DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19949/S060
NDA 20090/S044

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Shai Srulovich, PharmD, RPh
Senior Manager, Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017

Dear Dr. Srulovich:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 2, 2014, received May 2, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product	NDA Number	Supplement Number
Diflucan (fluconazole) Tablets	19949	S-060
Diflucan (fluconazole) Powder for Oral Suspension	20090	S-044

We acknowledge receipt of your amendment dated October 20, 2014.

These supplemental applications propose revisions to the **PRECAUTIONS** and **DOSAGE AND ADMINISTRATION** sections of the package insert. The **PRECAUTIONS** section**, Drug Interactions** subsection, has been updated to include information regarding fluconazole and verapamil. The **DOSAGE AND ADMINISTRATION** section has been revised to include a statement regarding the dosing regimen for patients with renal impairment. Additionally, revisions have been made to the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection regarding susceptibility testing and to the **REFERENCES** Section.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA

automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Office of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
10/30/2014